

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

MEYERTONS, HOOD, KIVLIN, KOWERT & GOETZEL, P.C.
Attn: Meyertons, Eric B.
P.O. Box 398
Austin, TX 78767-0398
ETATS-UNIS D'AMERIQUE

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

<p>Date of mailing (day/month/year) 09/09/2008</p>	
<p>Applicant's or agent's file reference: 5943-01005</p>	<p>FOR FURTHER ACTION See paragraphs 1 and 4 below</p>
<p>International application No.: PCT/US2008/051346</p>	<p>International filing date (day/month/year) 17/01/2008</p>
<p>Applicant: FLEXUSPINE, INC. Pull: AS-AP 11/10/08 12/19/08</p>	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, within **20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Josephina Tschuck

To: DR for US IPS

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the international Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 5943-01005	FOR FURTHER ACTION		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2008/051346	International filing date (day/month/year) 17/01/2008	(Earliest) Priority Date (day/month/year) 19/01/2007	
Applicant FLEXUSPINE, INC.			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 7 sheets.

☐

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of:

☒

the international application in the language in which it was filed

☐

a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

- b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6b(a)).

- c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box No. II)

3. ☒ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

☒

the text is approved as submitted by the applicant

☐

the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☐

the text is approved as submitted by the applicant

☒

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 12, 13

☐

as suggested by the applicant

☐

as selected by this Authority, because the applicant failed to suggest a figure

☒

as selected by this Authority, because this figure better characterizes the invention

- b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2008/051346

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

A stabilization system for a human spine is provided. The stabilization system may include one or more dynamic interbody devices and/or one or more dynamic posterior stabilization systems. The dynamic interbody devices may provide for coupled axial rotation and lateral bending of vertebrae adjacent to the dynamic interbody devices. The dynamic posterior stabilization systems may provide resistance to movement that mimics the resistance provided by a normal functional spinal unit.

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/44 A61F2/46

A61B17/17

A61B17/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/116851 A (KINETIC SPINE TECHNOLOGIES INC [CA]; DUPLESSIS STÉPHAN J [CA]; SEKHON) 9 November 2006 (2006-11-09) paragraphs [0009], [0055] - [0073], [0089]	1,4,6,7,9
Y		5,8
X	WO 2004/019828 A (MATHYS MEDIZINALTECHNIK AG [CH]; BAUMGARTNER DANIEL [CH]; BURRI ADRIAN) 11 March 2004 (2004-03-11) pages 7-8	1-4
X	WO 2006/066198 A (SAVAGE BIOMECHANICS INC O [US]; PAXSON ROBERT D [US]; NILSSON CARL M []) 22 June 2006 (2006-06-22) page 6, line 22 - page 10, line 5	1,9
Y	US 2006/089717 A1 (KRISHNA MANOJ [GB] ET AL) 27 April 2006 (2006-04-27) paragraphs [0047], [0048], [0062]	5,8

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

15 May 2008

Date of mailing of the international search report

09/09/2008

Name and mailing address of the ISA/
European Patent Office, P.B. 5816 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Buchmann, Gerhard

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/051346

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 65-90, 104
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-9

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-9

An intervertebral device comprising two members being movable with respect to each other, allowing coupled lateral bending and axial rotation.

2. claims: 10-17

An intervertebral device comprising two members having guide surfaces and being movable with respect to each other, allowing lateral bending.

3. claims: 18-25

An intervertebral device comprising two members having guide surfaces and being movable with respect to each other, allowing axial rotation.

4. claims: 26-30

An intervertebral device comprising two pairs of members being movable with respect to each other, allowing coupled lateral bending and axial rotation.

5. claims: 31-38

An intervertebral device comprising two coupled pairs of members having guide surfaces and being movable with respect to each other, allowing lateral bending.

6. claims: 39-46

An intervertebral device comprising two coupled pairs of members having guide surfaces and being movable with respect to each other, allowing axial rotation.

7. claims: 47-52

An intervertebral device comprising two members being movable with respect to each other, the first member having a larger width than the second member.

8. claims: 53-64

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

An intervertebral device comprising three members being movable with respect to each other, allowing coupled axial rotation and lateral bending between the first and second member, and allowing flexion/extension between the second and the third member, the first member having a larger width than the second member.

9. claims: 91-102

An intervertebral device comprising two members being movable with respect to each other by interacting grooves and ridges, so that axial rotation causes lateral bending or vice versa.

10. claim: 103

A combination of a dynamic posterior stabilization system and a dynamic interbody device.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2008/051346

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2006116851	A	09-11-2006	AU 2006243712 A1	09-11-2006
			CA 2607314 A1	09-11-2006
			CN 101170970 A	30-04-2008
			EP 1879528 A1	23-01-2008
			KR 20080027240 A	26-03-2008
			US 2008058944 A1	06-03-2008
WO 2004019828	A	11-03-2004	AU 2002322960 A1	19-03-2004
			CA 2497278 A1	11-03-2004
			CN 1665459 A	07-09-2005
			EP 1534193 A1	01-06-2005
			JP 2005537053 T	08-12-2005
			US 2006036326 A1	16-02-2006
WO 2006066198	A	22-06-2006	EP 1845902 A1	24-10-2007
			US 2006149372 A1	06-07-2006
US 2006089717	A1	27-04-2006	EP 1647243 A2	19-04-2006
			EP 1738721 A2	03-01-2007
			EP 1738722 A2	03-01-2007
			US 2008033562 A1	07-02-2008
			US 2006085076 A1	20-04-2006

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2008/051346

International filing date (day/month/year)
17.01.2008

Priority date (day/month/year)
19.01.2007

International Patent Classification (IPC) or both national classification and IPC
INV. A61F244 A61F246 A61B17/17 A61B17/70

Applicant
FLEXUSPINE, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Buchmann, Gerhard

Telephone No. +49 89 2399-2288



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2008/051346

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 65-90, 104, 10-64, 91-103

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 65-90, 104, 10-64, 91-103

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-9

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>5,8</u>
	No: Claims	<u>1-4,6,7,9</u>
Inventive step (IS)	Yes: Claims	<u>-</u>
	No: Claims	<u>1-9</u>
Industrial applicability (IA)	Yes: Claims	<u>1-9</u>
	No: Claims	<u>-</u>

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item III.

Claims 65-90 and 104 of the present application define methods of stabilizing vertebrae, comprising the step of inserting a dynamic interbody device. This represents a method for surgical treatment of the human body in the sense of Rule 67.1 (iv) PCT. Therefore, no examination is carried out for this claim/these claims according to Art. 34 (4)(a)(I) PCT.

Re Item IV.

The separate inventions/groups of inventions are:

1. Claims 1-9: An intervertebral device comprising two members being movable with respect to each other, allowing coupled lateral bending and axial rotation.
2. Claims 10-17: An intervertebral device comprising two members having guide surfaces and being movable with respect to each other, allowing lateral bending.
3. Claims 18-25: An intervertebral device comprising two members having guide surfaces and being movable with respect to each other, allowing axial rotation.
4. Claims 26-30: An intervertebral device comprising two pairs of members being movable with respect to each other, allowing coupled lateral bending and axial rotation.
5. Claims 31-38: An intervertebral device comprising two coupled pairs of members having guide surfaces and being movable with respect to each other, allowing lateral bending.
6. Claims 39-46: An intervertebral device comprising two coupled pairs of members having guide surfaces and being movable with respect to each other, allowing axial rotation.
7. Claims 47-52: An intervertebral device comprising two members being movable with respect to each other, the first member having a larger width than the second member.
8. Claims 53-64: An intervertebral device comprising three members being movable

- with respect to each other, allowing coupled axial rotation and lateral bending between the first and second member, and allowing flexion/extension between the second and the third member, the first member having a larger width than the second member.
9. Claims 91-102: An intervertebral device comprising two members being movable with respect to each other by interacting grooves and ridges, so that axial rotation causes lateral bending or vice versa.
10. Claim 103: A combination of a dynamic posterior stabilization system and a dynamic interbody device.

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

The features which are common to the inventions 1-10 are:

An intervertebral device comprising two members being movable with respect to each other.

These common features, however, are well known to a person skilled in the art.

The inventions 1-10 provide, in different combinations, for the following features making a contribution over the prior art:

1. The two members allowing coupled lateral bending and axial rotation.
2. The two members allowing lateral bending.
3. The two members allowing axial rotation.
4. The two members being combined with a second pair of members.
5. The two members being coupled to a second pair of members.
6. The first member having a larger width than the second member.
7. The two members being combined with a third, intermediate, member.
8. The two members having grooves and ridges, interacting so that axial motion causes lateral bending or vice versa.

The different special technical features solve the following different problems:

1. To provide an intervertebral implant which mimics the natural motion between the vertebrae.
2. To provide an intervertebral implant which allows for lateral bending of the spinal

- column.
3. To provide an intervertebral implant which allows for axial rotation of the spinal column.
 4. To provide an intervertebral implant which has a lower profile during the implantation procedure.
 5. To inhibit migration of the implants.
 6. To inhibit subsidence as far as possible.
 7. To provide an intervertebral implant which has an improved geometry of possible motions.
 8. To provide an intervertebral implant which mimics the motion restriction normally provided by the facet joints.

Each pair of the above inventions differs in at least one of the special technical features 1-8.

Hence, the above 10 inventions have neither common features making a contribution over the prior art, nor corresponding features which would solve the same problem.

Therefore the above 10 inventions are not linked by a single inventive concept in the sense of Rule 13 PCT.

Re Item V.

- 1 Reference is made to the following document:
 - D1 : WO 2006/116851 A (KINETIC SPINE TECHNOLOGIES INC [CA]; DUPLESSIS STEPHAN J [CA]; SEKHON) 9 November 2006 (2006-11-09)
 - D2: WO 2004/019828 A (MATHYS MEDIZINALTECHNIK AG [CH]; BAUMGARTNER DANIEL [CH]; BURRI ADRIAN) 11 March 2004 (2004-03-11)
 - D3: WO 2006/066198 A (SAVAGE BIOMECHANICS INC O [US]; PAXSON ROBERT D [US]; NILSSON CARL M []) 22 June 2006 (2006-06-22)

2 INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the

subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (the references in parentheses applying to this document):
A dynamic intervertebral disc comprising a first member (12) and a second member (14) being movable with respect to each other to allow coupled lateral bending and axial rotation of the vertebrae (para. 0009).

Therefore, the subject-matter of claim 1 is already known from document D1.
Also documents D2 and D3 disclose all features defined in claim 1.

3 DEPENDENT CLAIMS 2-9

Dependent claims 2-9 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

See the documents cited in the international search report and the corresponding passages.

Re Item VII.

The independent claim is not written in the two part form (Rule 6.3(b) PCT), which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

The features of the claims are not provided with reference signs placed in parentheses to increase the intelligibility of the claims (Rule 6.2(b) PCT). This applies to both the preamble and characterising portion (see the PCT Guidelines 5.05).

The documents D1-D3 are not identified in the description and the relevant background art disclosed therein is not discussed (Rule 5.1(a)(ii) PCT).

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2008/051346

The passage on page 39, lines 15-16 renders the application unclear with respect to the intended scope of protection (PCT Guidelines 5.30).

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information

For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.

Amending claims under Art. 19 PCT

Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.

Filing a demand for international preliminary examination

In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).

If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).

Filing informal comments

After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.

End of the international phase

At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPEA (international preliminary examination report).

Relevant PCT Rules and more information

Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003